domains including 93 items. We enhanced our previous selection of only European HTA agencies (IQWiG, DAHTA@DIMDI, NICE, HAS, SBU) by AHRQ, MSAC, LBI, BIQG / GOEG, CADTH, DECIT-CGATS, HITAP. Information was collected and compared quantitatively, choosing the item 'cost-effectiveness threshold' as key information. Additionally, HTA agencies' methodological guidelines were extracted for PCM relevant information. Finally, information was entered into the database and compared qualitatively. **RESULTS:** First five agencies differed highly in eight domains (organization scope, processes, methods, dissemination, decision, implementation, and impact). They agreed in only 17-40%. Enhancement by further agencies indicates continued heterogeneity. UK (US$32.000-48,000) and Thailand (US$9,866) indicated explicit but generic (i.e. not specific to disease or type of technologies) thresholds; implicit use was identified in five countries (Australia, Brazil, Canada, Sweden, USA). Germany explicitly uses disease-specific cost-effectiveness ratios. In none of the included countries cost-effectiveness thresholds specific to personalized medicine and/or oncology were identified, even though we found exception rules in UK. **CONCLUSIONS:** Based on a systematic and comprehensive contextual framework displaying HTA in 10 countries of four continents we identified large heterogeneity in the application of HTA. Specific guidance for innovative and costly cancer interventions is lacking.

PHP125

CLINICAL TRIAL LEARNING CURVES MAY IMPACT BOTH CLINICAL AND ECONOMIC OUTCOMES, AND INFLUENCE HEALTH TECHNOLOGY ASSESSMENT AND REIMBURSEMENT DECISION MAKING

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OBJECTIVES: We previously presented evidence suggesting that clinical trial learning curves may affect clinical outcomes in patients in drug trials. In the current analysis, we demonstrate the potential effect of learning curves on economic outcomes (specifically, cost-effectiveness). **METHODS:** The PROWESS trial, which evaluated drotrecogin alpha (DrotAA) for severe sepsis, was identified in our previous study and was chosen for further analysis based on several considerations: a published analysis suggested that a clinical trial learning curve may have had a substantial effect on outcomes in a subgroup of patients (APACHE II < 25); and a published cost-effectiveness analysis (which did not account for the learning curve effect) was transparent and easily replicable. Furthermore, a health technology appraisal (HTA) of DrotAA conducted in the UK cited the cost-effectiveness analyses, which suggested that the incremental cost per quality-adjusted life year for patients with APACHE II scores < 25 was $>$ US$400,000. Similarly, an Australian reimbursement decision excluded this patient subpopulation from coverage citing unacceptable cost-effectiveness. We replicated the cost-effectiveness analysis for DrotAA, and used it to model the cost-effectiveness of DrotAA in the subgroup of patients with APACHE II < 25, both with and without the patients enrolled earlier in the trial and thus potentially affected by the learning curve. **RESULTS:** When patients who may have been affected by the trial learning curve were excluded from the analysis, cost-effectiveness of DrotAA improved significantly, from US$411,333 per LYG with all patients with APACHE II score < 25 to US$46,395 per LYG when the first block of patients enrolled at each site was removed from the analysis. **CONCLUSIONS:** Clinical trial learning curves potentially affect both clinical and economic outcomes, and impact reimbursement decisions. Consideration of learning curves may be important in HTAs and reimbursement decisions, particularly when evaluating trial data in which learning curves are more likely to be present.

PHP126

OVERVIEW OF HTA PROCESS AND IMPLEMENTATION AMONG HEALTH STAKEHOLDERS IN BOSNIA AND HERZEGOVINA – SURVEY BASED RESEARCH

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OBJECTIVES: Health Technology Assessment (HTA) is relatively new concept for Bosnia and Herzegovina health care decision-makers. Decision on reimbursement of medicines and other technologies are made on different levels due to decentralised health system and by different stakeholders (Entities/Cantonal Health Insurance Funds-HIF, Hospitals, Ministries of Health-MoH). Objective of this survey was skreening of current situation and understanding of HTA principles, process and implementation in decision making proces among key stakeholders. **METHODS:** A 9-question survey with INAHTA definition of HTA provided has been distibuted to 50 stakeholders with potential influence on reimbursement decisions. Survey include questions on current practices and process of reimbursement decisions, existance of HTA body/commission, criteria for decisions and reasons for de-listing of reimbursed technologies. Deadline for response was two months. **RESULTS:** Overall response rate was 30%; 50% (6/12) of Ministries of Health, 42% (5/12) Health Inusrance Funds and 17% (4/24) Hospitals respond. 73% respondents use criteria for decisions on drug reimbursement, and 67% in case of other technologies. Mostly used criteria are expert opinions (47%) and pharmacoeconomic studies provided by the manufacturer/presentative (40%), while 33% use referal pricing as criteria. Most of respondents use mixed criteria. HTA bodies in form of commission/expert boards are established in 7 institutinons, mostly in MoH and HIFs. This bodies consist of physitians and pharmacists, and only two of respondents include economicst into these bodies. Similar situation is observed in case od medical devices and other technologies reimbursement decisions. De-listing is recorded in 40% respondents but main reason was production discontinuation. **CONCLUSIONS:** Although the response rate is low, it allows conclusions that correlate with the experience and current practices. There is a need for a systematic approach to HTA and adoption of clearer criteria for reimbursement decision-making. Establishing HTA bodies consisted of trained professionals would improve the HTA process and reimbursement decisions.

PHP127

IMPACT OF PATIENT ACCESS SCHEMES ON NICE AND SMC GUIDANCE

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OBJECTIVES: To determine whether the use of patient access schemes (PAS) in the provision of NICE and SMC guidance could be brought into greater alignment, leading to greater cost savings. **METHODS:** From a survey of technology appraisals published on the SMC and NICE websites, the total number involving a PAS has been assessed. Further, if a PAS is included for a particular drug in one set of guidance, a comparison has been made of the equivalent guidance by the other body. There are differences between NICE and SMC roles: NHS England should fund/resource treatments recommended by NICE; NHS Scotland is expected to consider SMC advice, but it is not binding. SMC issues guidance on all newly licensed medicines, unlike NICE, which prioritizes guidance where it is most needed. **RESULTS:** The list of positive NICE appraisals based on the inclusion of a PAS consists of 15 pharmaceuticals, while the same list for the SMC includes only nine. Most products with a PAS are included in both sets of guidance, with seven of the nine SMC PAS also included in the NICE guidance. The remaining two with SMC PAS have not been assessed by NICE. Of eight NICE PAS not included in SMC guidance, four were accepted/accepted with restricted use, e.g. lenalidomide. The NICE PAS ensures that if a patient receives $>$26 treatment cycles, the manufacturer will cover the cost of further cycles. No PAS is included in SMC guidance; therefore, NHS Scotland has no cost cap. **CONCLUSIONS:** PAS are more frequently included in manufacturers' submissions to NICE than to SMC. SMC has approved a number of therapies for which NICE required a PAS to improve the economic argument. Therefore, for these drugs, NHS Scotland could potentially achieve greater cost savings if SMC demanded similar PAS to those required by NICE.

PHP128

IN DEPTH ANALYSIS OF HEALTH TECHNOLOGY INCORPORATION IN BRAZIL. IS THERE A COST-EFFECTIVENESS MEASURE OF THRESHOLD?

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OBJECTIVES: Recently, a study conducted in Brazil (Teich et al, 2010) evaluated the decisions and process submitted to the Brazilian Commission on Health Technology Incorporation (CITEC), classifying them according to therapeutic area, response type and applicant. The study concluded that there is no clear definition of priorities for the incorporation of a new technology; however, it did not analyze a possible cost-effectiveness threshold for decision making. Therefore, the present study aims to evaluate the existence of economic analysis which supports CITEC decisions and map possible trends. **METHODS:** CITEC decisions and technologies for analysis were obtained from the updated list available at the Ministry of Health website. Only economic studies (cost-effectiveness/utility, cost-minimization and budget impact) from the Brazilian perspective were included and the following databases were consulted: "Medline", "SciSearch", "Embase", "Biosis Preview" and "ISPOR Outcomes Research Digest". **RESULTS:** Technologies were classified in 3 categories: incorporated, not-incorporated and in-analysis; and the results from economic evaluations were classified into: dominant /cost-saving; up to $Brz30,000; $Brz30,000-50,000; $Brz50,000-100,000 and above $Brz100,000 per outcome (ideally QALY or LY, but others were considered). Of the technologies that were not-incorporated, only 2 presented economic evaluation from Brazilian perspective: 1 study with incremental cost up to $Brz30,000 and 1 between $Brz50-100,000. From incorporated technologies, only 20% presented economic evaluations with results belonging to all categories (including above $Brz100,000 per outcome). From technologies in analysis, 20% had economic studies, being most of them dominant or cost-saving. **CONCLUSIONS:** Apparently, there is no criterion for health technology assessment and inclusion of new technologies in Brazilian public system (SUS) and also a lack of quality in the economic analysis conducted. Therefore, besides the absence of priorities, the absence of criteria for technology incorporation could potentially lead the system to be inefficient, spending more money than necessary and not adopting cost-saving therapies.

PHP129

SOCIETAL PREFERENCES FOR HEALTH TECHNOLOGY DISINVESTMENT POLICY: VIEWS OF SCOTTISH TAXPAYERS – A QUALITATIVE STUDY

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OBJECTIVES: Increasingly challenging economic times require challenging decisions to be made regarding health technology disinvestment. Insufficient evidence exists on societal preferences for disinvestment in publicly-funded health care systems. This research sought to explore the acceptability of disinvestment to Scottish taxpayers, their preferences, and whether taxpayer loss aversion is a relevant factor for disinvestment policy development. **METHODS:** Qualitative interviews were conducted with a sample of Scottish taxpayers. Interviews were split into four parts to progress thematic discussion from basic to complex, examine consistency and identify responses potentially indicative of loss aversion. Participants were asked about their general views on the NHS and disinvestment (Part 1), scenario-based questions on disinvestment (Part 2), to freely discuss the disinvestment issues they considered important and who they thought should be involved in making decisions (Part 3), and further scenario-based questions on health technology investment (Part 4). **RESULTS:** Twelve interviews were undertaken. Responses were generally consistent. Scottish taxpayers notionally accepted disin-

vestment, recognising the NHS budget (providing free universal healthcare) was not unlimited. Local organisation of disinvestment policy was preferred, though some national co-ordination was felt necessary to retain equity across geographical jurisdictions. Technologies of unproven or negligible clinical benefit, or obsolete technologies were cited as disinvestment priorities. Respondents preferred disinvestment decisions be clinician-led. Other decision-making groups (e.g. patients) were expected to be biased or not sufficiently knowledgeable about the relevant issues. When existing technologies conferred clinical benefits to (even small numbers of) patients, responses suggested loss aversion, even under circumstances of increased risks alongside these benefits. Biases are uncontrolled when using a qualitative methodology to explore these issues. **CONCLUSIONS:** To maximise acceptability to taxpayers, disinvestment policy-making in Scotland should prioritise technologies of comparatively low or unproven benefit. Decisions should be locally-based and clinician-led. Future research on disinvestment should utilise quantitative, preference-elicitation methods to minimise potential biases.

PHP130

USING ECONOMIC EVIDENCE AND STAKEHOLDER'S PARTICIPATION IN DECISION MAKING ON BENEFIT PACKAGE OF PUBLIC HEALTH INSURANCE IN THAILAND

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OBJECTIVES: With the increasing demands for health care from aging society and rapid technological advancement, the National Health Security Office (NHSO) of Thailand demands for the development of systematic, transparent, and participatory processes for selection of new health interventions to be included into the benefit package of universal health coverage (UC) scheme. This study reviews and describes experiences in the development of guidelines for economic evaluation and participatory process of key stakeholders in submission and topic selection of new health interventions into the UC benefit package. Lessons learnt from this initiative are drawn in order to share experiences of Thailand to other developing countries. **METHODS:** Research methods comprise comprehensive literature reviews, focus group discussion, and brainstorming meeting among key stakeholders, working groups, and subcommittee members. **RESULTS:** Research findings indicate that the draft guideline produced by several rounds of stakeholder consultations has been gradually accepted and adjusted by policy makers and key stakeholders. Key features of the guideline comprise a) transparency in topic selection for economic appraisal with full engagement of key stakeholders; b) economic evaluation on selected interventions using incremental cost-effectiveness ratio (ICER); c) budget impact analysis. The ICER threshold of 1 GDP per capita for QALY gained has been applied by the Benefit Package Subcommittee of NHSO. The six criteria for prioritization of topics were adopted in consensus by stakeholder consultations. In Fiscal year 2010 and 2011, this guideline was successfully applied twice a year for topic selection, economic appraisal, and recommendations to the sub-committee and transmitted to NHSO Board for its final decision. **CONCLUSIONS:** This initiative not only produced and applied evidence informed decisions in a transparent manner; it also strengthened and sustained institutional capacities in generating evidence on ICER, budget impact assessment and other ethical social considerations. The NHSO subcommittee is the platform for interchange between evidence and policies.

PHP131

HOW CAN PHARMA INDUSTRY PREPARE ITSELF FOR THE CHANGING PRICING AND REIMBURSEMENT LANDSCAPE OF ORPHAN DRUGS IN EU?

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OBJECTIVES: Healthc are reforms are inherent in any health care system across the globe in order to take into account changes and developments worldwide on new ways to evaluate innovative medicines. This has impacted drugs being launched in the rare disease space. The research is aimed to understand the dynamics in pricing and reimbursement environment of drugs launched in rare diseases in key European markets. **METHODS:** The research involved desk research as well as interviews with selected stakeholders in EU5, The Netherlands, Sweden, Finland and Romania. **RESULTS:** In the past it was orphan drugs were able to achieve a high price or favourable reimbursement status, largely due to International and National OD legislation. The results inferred that factors such as the level of unmet needs, severity of diseases, prevalence, innovation, clinical effectiveness influence the achievable price and reimbursement. To keep up to speed to the challenges of dynamic healthcare funding environments pharmaceutical companies have to ensure that the value of the product is well demonstrated with a clear value proposition. When products are launched in specific markets, the HTA bodies look for specific criteria to be fulfilled (e.g. the SMC in the UK or HAS in France). **CONCLUSIONS:** Orphan drugs are facing significant challenges in the future. However, opportunities still exist for novel compounds to reach the market place and have an impact on how rare diseases are treated. Low patient numbers, high levels of both disease severity and unmet need and public perception can help boost the economic argument for Orphan Drug Approval and enable strong market access.

Health Care Use & Policy Studies – Patient-Registries & Post-Marketing Studies

PHP132

USE OF A DISEASE SPECIFIC QUALITY OF LIFE TOOL IN A QUALITY ASSURANCE SCHEME FOR DAY CASE HERNIA SURGERY

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OBJECTIVES: Outpatient services in Germany are less controlled by external quality assurance programs. Comprehensive outcome data for benchmarking or health-care decision-making are missing e.g. for day case surgery. A quality-of-life instrument specific to hernia repair with mesh has been recently proposed (Carolinas Comfort Scale, CCS). This study evaluates the integration of CCS as part of a multicentre quality assurance scheme for outpatient surgery. **METHODS:** Sixteen ambulant centres developed a web-based quality assurance scheme for hernia day surgery in Germany. In an evaluation phase, all patients which were intended to treat with 3-dimensional meshes, were registered with consensus into a database through a web-based portal. CCS questionnaires were mailed to patients 4 and 12 weeks after surgery. Patients were requested to send pseudonymized responses to an independent party for inputting answers into the database. Clinical examinations were made 4 and 12 weeks postoperatively. Additional follow-up is planned 52 weeks after surgery. CSS consists of 23 questions in 7 activity- categories and 3 dimensions: sensation of mesh, movement limitations, pain. **RESULTS:** During the first year (Oct 2009 to Sept 2010) 1429 patients were registered (1271 male, 158 female, median age 53 years) and treated for primary (88%) or recurrent (11%) hernia. 1300 (90%)/1246 (87%) patients were clinically reviewed 4/12 weeks after surgery. 1072 (75%) /1002 (70%) questionnaires were retrieved 4/12 weeks after surgery. Patient satisfaction rate was 98%. CCS scores are shown to be decreased from 4 to 12 weeks in all dimensions (Sensation: 0.51 to 0.35, Movement: 0.40 to 0.20, pain: 0.45 to 0.26). **CONCLUSIONS:** CCS, a short, hernia-specific quality-of-life questionnaire, is easy to use and well accepted by patients. It is shown to be a feasible instrument to evaluate patient reported outcome after day-case hernia surgery in a web-based multicentre quality assurance system.

Health Care Use & Policy Studies – Population Health

PHP133

LEVELS OF POPULATION RISK STRATIFICATION BASED ON THE COST OF CARE IN PATIENTS WITH CHRONIC DISEASES

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OBJECTIVES: To determine the population risk stratification based on the cost of care (health resource use) in patients with chronic diseases in primary health care (PC). **METHODS:** Multi-center observational design. We included all patients from 6 centers of PC that demanded assistance in 2010 managed by Badalona Serveis Assistencials SA (health organization). The risk population was defined beginning from the complexity (co-morbid chronic [CC]) and fragility (socio-demographic and clinical criteria). Main measures: services (medical, paediatric), chronic co-morbidity (CC) and direct cost model. From a group of experts identified the different chronic conditions and population risk levels: Level 1 (no CC), level 2 (1-2 CC), level 3 (3-4 CC) and level 4 (≥ 5 CC). Fixed (operation) and variable costs were considered. Statistical analysis: linear regression model (coefficient of determination [R2], dependent variable: health care costs) and principal components, $p<0.05$. **RESULTS:** We included 83,090 patients, mean age 40.9 years, women: 53%. The total cost was 56.1 million / EUR. The average / unit cost: 675.3 euros. The cost for drugs was 41%. Stratification levels: level 1 (N = 36,859, 44.4%, €283.9), level 2 (N = 32,644, 39.3%, €694.8), Level 3 (N = 10019, 12.1%, €1461.6, and level 4 (N = 3568, 4.3%, €2331.2). Musculoskeletal diseases (38.1%), mental (31.6%) and cardiovascular (30.4%) were the most frequent, $p<0.001$. Predictive model (R2): age = 23.4%, age-sex = 24.1%, age-sex-CC = 41.8% (medical: 47.9%; Paediatrics: 15.1%, $p<0.001$). It details the complexity and fragility of the patients for each level of stratification and clinical services. **CONCLUSIONS:** The CC is associated with increased healthcare costs. The number of co-morbidities explains much of the costs. Knowledge of the risk / complexity / fragility of the patients should allow preventive intervention strategies.

Health Care Use & Policy Studies – Prescribing Behavior & Treatment Guidelines

PHP134

COMPARISON OF THE KNOWLEDGE IN STANDARD TREATMENT GUIDELINES AMONG MEDICAL PRACTITIONERS AND MEDICAL STUDENTS

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OBJECTIVES: Introduction of module in rational use of medicine (RUM) to pharmacology curriculum needs analysis of existing knowledge among health care workers. The knowledge and attitudes of medical practitioners (MPs) and medical students (MSs) on Standard Treatment Guidelines (STG) were assessed. **METHODS:** Forty-two MPs and 120 MSs were given pretested structured questionnaire on STG and core policies of RUM. **RESULTS:** Results showed that only 78 % of MPs were confident about their knowledge in STG and 7% of them were not attentive. Knowledge of MPs and MSs showed 78% and 84% on contents of STG while the knowledge in core policies was 73% and 34% respectively. More than 99% of MSs and 71% of MPs were attentive on the inclusion of clinical features of the illness in STG. knowledge on updating and significance of STG as guidance for new prescribers of MPs were 84% and 88% respectively while 96 % of MSs had acquainted in those two areas. Both groups had good knowledge on STG is not an accordance with personnel experience (MPs-71%, MSs-74%). 80% of MSs and 75% MPs discerned that common treatment practices is not an inclusion criteria for STG. **CONCLUSIONS:** We found that MSs had good knowledge about the contents of STG and skills in application in RUM are limited. MPs were detailed on core policies & application of STG